UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456 CIVIL ACTION NO. 01-CV-12257-PBS Judge Patti B. Saris
THIS DOCUMENTS RELATES TO ALL ACTIONS	

BAYER CORPORATION'S SEPARATE REPLY MEMORANDUM
IN SUPPORT OF ITS MOTION TO DISMISS

Plaintiffs do not dispute that the *only* Bayer products they allegedly purchased are Cipro® and Cipro XR® (hereinafter "Cipro"), which are self-administered pills not covered by Medicare Part B. Pl. Sep. Opp. at 36-39. Nor do plaintiffs dispute the fact that the only paragraph in the AMCC that even mentions Cipro -- ¶ 289 – simply recites the settlement of a government inquiry involving Medicaid "best prices," *not* AWP. In response, Plaintiffs continue to rely on fraud allegations that concern *entirely different* Medicare Part B drugs they never purchased. Plaintiffs thus have again failed to meet the Court's plainly-stated test for standing to proceed against Bayer: they have not identified a plaintiff that has purchased a specified Bayer drug along with "the allegedly fraudulent AWP" for that same drug. *In Re Pharm. Indus. AWP Litig.*, 263 F. Supp. 2d 172, 194 (D. Mass. 2003). Bayer should again be dismissed from this action.

Plaintiffs' response repeatedly relies on AMCC allegations concerning Bayer's 2001 settlement with the United States and virtually all the States concerning the AWP of certain Bayer drugs. *See* Pl. Sep. Opp. at 36-37. Yet this settlement, as the AMCC allegations on their face establish, did not involve Cipro. Instead, the settlement involved four different Bayer products – Kogenate®, Koate-HP®, Konyne-80®, and Gamimune® – all of which, unlike Cipro, are physician-administered drugs covered under Medicare Part B. *See* AMCC, ¶¶287, 290, 293-95, 298. Plaintiffs cannot mix and match the allegations of fraud as to these four Part B products that were resolved in the 2001 settlement – which plaintiffs undisputedly did not purchase – in order to obtain standing and satisfy the May 13 Order's requirements for Cipro, the one, non-Part B Bayer drug plaintiffs allegedly purchased. *See In re Pharm. Indus. AWP Litig.*, 263 F. Supp. 2d at 194 (plaintiffs must "clearly and concisely" state what the fraud is for a drug they purchased); *Asarco, Inc. v. Kadish,* 490 U.S. 605, 615 (1989) (the doctrine of standing is not a "gaming device" that plaintiffs may surmount merely by aggregating allegations).

As a fallback, Plaintiffs attempt to reinvent the one paragraph that even mentions Cipro in the AMCC. That one-sentence paragraph asserts without elaboration that, "in April 2003," Bayer made a settlement payment to the government "for alleged overcharges involving its

antibiotic Cipro and its high blood pressure drug Adalat." AMCC ¶ 289. This 2003 settlement, however, had nothing to do with AWP. Instead, in that settlement, the federal government, 49 states, and the District of Columbia settled and released their claims under the Medicaid program for overstating Cipro® and Adalat® "best prices," as defined by Medicaid. *See* Exhibit 1, Settlement Agreement and Release §§ II(H), III(D)(2).[1] This Medicaid "best price" settlement makes no mention of AWP. Plaintiffs do not, and could not, assert standing to bring such Medicaid "best price" claims, which concern rebates payable to the States, not to any private individuals or health plans.[2]

Plaintiffs' response is to redraft the AMCC, claiming, first, that the AMCC alleges that this settlement in fact did involve AWP (Pl. Sep. Opp. at 38), and, second, that the "best price" inflation raised in the 2003 settlement "also had the effect of inflating the AWP for Cipro." *Id.* Neither response has any merit.

First, even if the AMCC had alleged that the 2003 settlement involved AWP – which the AMCC plainly does not – it is well-settled that the settlement document itself controls to the extent it contradicts allegations in the AMCC. *E.g. Clorox Co. v. Proctor & Gamble Commer. Co.*, 228 F.3d 24, 32 (1st Cir. 2000) (document referenced by complaint "trumps" contradictory assertions in the complaint). And here the 2003 settlement contains not one word about AWP.[3]

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[1] In light of plaintiffs' specific reference to, and reliance on, this settlement in the AMCC, the Court may take judicial notice of its contents in considering a Rule 12(b)(6) motion. *See Watterson v. Page*, 987 F.2d 1, 3 (1st Cir. 1993); *Romani v. Shearson Lehman Hutton*, 929 F.2d 875, 879 n.3 (1st Cir. 1991).

[2] As the Court is aware, a number of such Medicaid "best price" cases, brought by certain State and local governments, currently form a part of this MDL.

[3] In addition, the settlement itself provides no proper foundation for plaintiffs' claims, both because it expressly states that Bayer denies wrongdoing, and because the federal rules preclude its use to establish fault. Ex. 1, § II(J); *see Advanced Cardiovascular Systems, Inc. v. Scimed Life Systems*, 63 F. Supp. 2d 1064, 1083 (N.D. Cal. 1999) (settlement agreements "provide no support" for allegations "because they do not include admissions by [defendant] or findings of liability"); *McInnis v. A.M.F., Inc., et al.*, 765 F.2d 240, 247 (1st Cir. 1985) (Fed.R.Evid. 408 bars use of settlements with third parties to establish liability). Indeed, allowing plaintiffs to plead fraud merely by raising the existence of a settlement would undermine federal policy encouraging such settlements.

Second, plaintiffs' new theory that alleged Medicaid "best price" inflation also somehow "inflates" AWP for Cipro is nowhere found in the AMCC. Plaintiffs cannot amend the AMCC through pleadings on a motion to dismiss. *E.g. Wright v. Ernst & Young, LLP*, 152 F.3d 169, 178 (2d Cir. 1998). Moreover, even if this vague allegation had found its way into the AMCC it would not meet the requirements of Rule 9(b) or this Court's May 13 Order. As is reflected in numerous complaints now before this Court brought by State and local governments, "best price" claims solely concern Medicaid, not Medicare, benefits. No reasonable inference can be drawn that allegations of improperly inflated Medicaid best prices have anything whatsoever to do with Medicare's AWP. Despite this Court's specific direction, therefore, plaintiffs utterly fail to allege a "fraudulent AWP" for Cipro®, the only drug they allegedly purchased from Bayer. Tellingly, plaintiffs fail to assert an allegedly fraudulent AWP "spread" for Cipro despite acknowledging that they have "numerous [Bayer] price lists setting forth spreads between AWPs and prices apparently offered to wholesalers, providers and other intermediaries," involving "hundreds of its drugs." AMCC ¶ 296.

In sum, plaintiffs fail to identify, as required, (1) a plaintiff (2) who purchased a Bayer drug (3) with a fraudulent AWP for that drug. Absent standing as to at least one Bayer drug, there is no basis, as this Court previously found in its May 13 Order, to allow plaintiffs to pursue class claims against Bayer for Medicare Part B drugs they undisputedly did not purchase. Bayer thus should again be dismissed from this case, this time with prejudice.

Dated: September 30, 2003

Respectfully submitted,

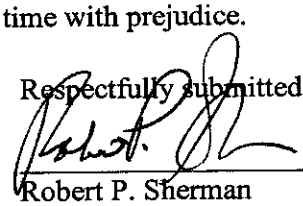

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Exhibit 1

SETTLEMENT AGREEMENT AND RELEASE

I. PARTIES

This Settlement Agreement ("Agreement") is entered into by the United States of America, acting through the United States Department of Justice and the United States Attorney's Office for the District of Massachusetts, and on behalf of the Office of Inspector General ("OIG-HHS") of the United States Department of Health and Human Services ("HHS"); Bayer Corporation ("Bayer"), an Indiana corporation with a principal place of business in Pittsburgh, Pennsylvania; and the Estate of George Couto (the "Relator"); through their authorized representatives. Collectively, all of the above shall be referred to as "the Parties."

II. PREAMBLE

A. WHEREAS, this Agreement addresses the United States' civil claims against Bayer for the conduct described in the currently pending allegations in United States ex rel. Estate of George Couto v. Bayer Corporation, Civil Action No. 00-10339-PBS (District of Massachusetts) (the "Civil Action"), for the conduct alleged in Preamble Paragraph H below, and for conduct described in filings in United States v. Bayer Corporation, Criminal Action No. [to be assigned](District of Massachusetts)(the "Criminal Action").

B. WHEREAS, on or about February 23, 2000, Relator George Couto filed the Civil Action in the United States District Court for the District of Massachusetts, entitled United States ex rel. George Couto v. Kaiser Permanente Medical Care Program; Kaiser Foundation Health Plan, Inc.; Kaiser Foundation Hospitals; Pacificare Health Systems, Inc.; Bayer Corporation U.S.A., Aventis Pharmaceutical Products, Inc.; Warner-Lambert Pharmaceutical Company, Inc.; Janssen Pharmaceutica, Inc.; Glaxo-Wellcome, Inc.; Forest Pharmaceuticals, Inc; Merck & Co., Inc.; Orth-

McNeil Pharmaceutical, Inc.; SmithKline Beecham, Inc.; Wyeth-Ayerst, Inc.; Eli Lilly & Co.; Schering-Plough, Inc.; and Mylan Laboratories, Inc., Civil Action No. 00-10339 (PBS). On or about November 14, 2000, the Relator filed a First Amended Complaint. Thereafter, in two separate stipulations of partial dismissal, the Relator voluntarily dismissed without prejudice, with the consent of the United States, all defendants except Bayer and, additionally, certain claims alleged against Bayer. On December 13, 2002, the United States intervened in the Civil Action against Bayer, and on January 24, 2003, filed a Complaint-in-Intervention. During the pendency of the litigation, the Relator died, and the Estate of George Couto has been substituted as the named Relator in the Civil Action;

C. WHEREAS, at all relevant times, Bayer marketed and sold pharmaceutical products nationwide, including among other drugs, two prescription drug products: (1) ciprofloxacin hydrochloride tablets, an antibiotic, marketed under the brand name Cipro®; and (2) nifedipine extended release tablets, an anti-hypertensive, marketed under the brand name Adalat CC® (collectively, "the drugs"). Bayer sold the drugs to various customers including, among others, health maintenance organizations ("HMOs"), hospitals, long term care providers, and chain pharmacies. Two HMOs that purchased the drugs from Bayer were Kaiser Permanente Medical Care Program ("Kaiser") and PacifiCare Health Systems ("PacifiCare"). PacifiCare purchased the drugs from Bayer through Prescription Solutions, a pharmacy benefit manager and wholly owned subsidiary of PacifiCare.

D. WHEREAS, effective August 1995, Bayer agreed to private label Cipro for Kaiser and to sell the private labeled Cipro to Kaiser at a discounted price. Effective April 1997, Bayer agreed to private label Adalat CC for Kaiser and to sell the private labeled Adalat CC to Kaiser at

a discounted price. Effective October 1998, Bayer agreed to private label Adalat CC for PacifiCare and to sell the private labeled Adalat CC to PacifiCare at a discounted price. The term "private labeled" as used herein, means drug product that Bayer sold to a purchaser to which Bayer affixed a label that substituted the purchaser's NDC number for Bayer's NDC number.

E. WHEREAS, at all material times, Bayer participated in the Medicaid Rebate Program, 42 U.S.C. § 1396r-8, which is part of the federal Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v. As a participant in the Medicaid Rebate Program, Bayer entered into a rebate agreement with the Secretary of the Department of Health and Human Services, which agreement is administered by the Health Care Financing Administration ("HCFA"), currently known as the Centers for Medicare and Medicaid Services ("CMS"), and Bayer's drug products were covered by state Medicaid plans that provided medical assistance for outpatient prescription drugs. 42 U.S.C. §§ 1396a(10)(A); 1396d(a)(12), and 1396r-8(a)(1). Under the Medicaid Rebate Program, Bayer generally agreed: (i) to report quarterly to HCFA its average manufacturer price and best price for its drug products, as defined by 42 U.S.C. §§ 1396r-8(k)(1) and 1396r-8(c)(1)(C); and (ii) to pay quarterly rebates to the states based on the product of (a) the units of each dosage form and strength paid for under the State Medicaid plan during the rebate period as reported by the state, and (b) the greater of the difference between the average manufacturer price and best price, or a minimum rebate percentage of the average manufacturer price, as further described in 42 U.S.C. § 1396r-8(c)(1).

F. WHEREAS, at all material times, Bayer participated in the Drug Pricing Program, 42 U.S.C. § 256b, which was enacted as part of the Public Health Service ("PHS") Act, 42 U.S.C. §§ 201-300gg-92. As a participant in the Drug Pricing Program, Bayer entered into an agreement

with HHS in connection with the pricing of its drug products sold to entities such as AIDS drug purchasing assistance programs, community health centers, hemophilia treatment centers, and disproportionate share hospitals, as defined in 42 U.S.C. § 256b(a)(4) (the "PHS entities"). Under the Drug Pricing Program and its agreement with HHS, Bayer generally agreed that the amount that Bayer required the PHS entities to pay for drug products would not exceed the average manufacturer price, as reported by Bayer to HCFA in the preceding calendar quarter, minus a specified rebate percentage that was derived in part, from the Medicaid rebate paid by Bayer in the preceeding calendar quarter for each drug, as further described in 42 U.S.C. § 256b(a).

G. WHEREAS, on or before April 16, 2003, or some other date as may be determined by the Court, Bayer has agreed to enter a plea of guilty pursuant to Fed. R. Crim. P. 11(c)(1)(C) to a one count Information alleging a violation of Title 21, United States Code, Sections 331(p), 333(a)(2) and 360(j) by failing to list a drug product with the FDA between August and December 1995, namely, Cipro, that was private labeled by Bayer for Kaiser.

H. WHEREAS, the United States contends that it has certain civil monetary claims against Bayer under the False Claims Act, 31 U.S.C. §§ 3729-33; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; Medicaid Rebate Program, 42 U.S.C. § 1396r-8; the Drug Pricing Program, 42 U.S.C. § 256b; other federal statutes, and/or common law doctrines as specified in Paragraph 2 below for engaging in the following conduct:

(i) The United States contends that, from Third Quarter 1995 through Third Quarter 2000, Bayer knowingly misreported its best price to HCFA and underpaid its Medicaid rebates for Cipro tablets by omitting the price of Cipro that was private labeled for Kaiser from its determination of best price;

(ii) The United States contends that, from Second Quarter 1997 through Third Quarter 2000, Bayer knowingly misreported its best price to HCFA and underpaid its Medicaid rebates for Adalat CC by omitting the price of Adalat CC that was private labeled for Kaiser and PacifiCare from its determination of best price;

(iii) The United States contends that, in First Quarter 1998, Bayer knowingly misreported its best price to HCFA and underpaid its Medicaid rebates for Adalat CC by omitting a $100,000 payment made by Bayer to Prescription Solutions in connection with Adalat CC;

(iv) The United States contends that, in May and June 1999, Bayer knowingly submitted false statements or records to the Office of Inspector General, Office of Audit Services, Department of Health and Human Services ("OIG-OAS") by (a) omitting material information about the price of Cipro tablets that were private labeled for Kaiser; (b) falsely stating that a higher priced package of Cipro was private labeled for Kaiser when it was not; and (c) falsely stating that the actual price at which Bayer sold Cipro to Kaiser was higher than Bayer's reported best price;

(v) The United States contends that, from First Quarter 1996 through First Quarter 2001, Bayer overcharged the PHS entities for Cipro tablets; and from Fourth Quarter 1997 through First Quarter 2001, Bayer overcharged the PHS entities for Adalat CC, all as a result of Bayer's underpayment of its Medicaid rebates as described in Preamble Paragraphs H(i), (ii) and (iii) above; and

(vi) The United States contends that Bayer knowingly failed to list the Cipro that Bayer private labeled for Kaiser with the FDA to conceal the private labeling arrangement from the FDA and customers of Bayer's Cipro.

Bayer's conduct as described in the currently pending claims in the Civil Action, this Preamble Paragraph H, and in the Criminal Action are hereafter referred to as the "Covered Conduct."

I. WHEREAS, OIG-HHS represents that it does not have an administrative claim for exclusion against Bayer under the provisions for mandatory exclusion from the Medicare, Medicaid and other federal health care programs, 42 U.S.C. § 1320a-7(a), for Bayer's conviction in the Criminal Action, but OIG-HHS contends that it has certain administrative claims for exclusion against Bayer under the provisions for permissive exclusion from the Medicare, Medicaid and other federal health care programs, 42 U.S.C. § 1320a-7(b), and the Civil Monetary Penalties Law, 42 U.S.C. §§ 1320a-7a for the Covered Conduct.

J. WHEREAS, other than such admissions as Bayer makes in connection with its plea to the Information to which Bayer has agreed to enter a plea of guilty, which Bayer admits, Bayer denies the allegations of the United States, OIG-HHS and the Relator as set forth herein and in the Civil Action, and Bayer denies that it has any liability or engaged in any wrongful conduct in connection with the Covered Conduct and the Civil Action.

K. WHEREAS, to avoid the delay, expense, inconvenience, and uncertainty of protracted litigation of these claims, the Parties mutually desire to reach a full and final settlement as set forth below.

III. TERMS AND CONDITIONS

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants, and obligations set forth below in this Agreement, and for good and valuable consideration as stated herein, the Parties agree as follows:

1. Bayer agrees to pay to the United States, the Participating States, and the PHS entites collectively, the sum of two hundred fifty-one million six hundred nine thousand two hundred dollars ($251,609,200), plus interest in an amount of twenty three thousand two hundred eighteen dollars ($23,218) for each day beginning March 25, 2003 and continuing until and including the day before complete payment is made (the "Settlement Amount"). This sum shall constitute a debt immediately due and owing to the United States, the Participating States, and the PHS entities on the Effective Date of this Agreement. This debt is to be discharged by payments to the United States, the Participating States, and the PHS entities under the following conditions:

A. Bayer shall pay to the United States the sum of one hundred thirty-three million one hundred sixty-nine thousand six hundred nineteen dollars ($133,169,619), plus interest in an amount of twelve thousand seven hundred seventy dollars ($12,770) for each day beginning March 25, 2003 and continuing until and including the day before complete payment is made (the "Federal Settlement Amount"). The Federal Settlement Amount shall be paid no later than seven business days after Bayer receives written payment instructions from the United States and following the latest of the dates on which the following occurs: (1) this Agreement is fully executed by the Parties and delivered to Bayer's attorneys, or (2) the Court accepts the Fed. R. Crim. P. 11(c)(1)(C) guilty plea in connection with the Criminal Action and imposes the agreed upon sentence.

B. Bayer shall pay to the Participating States the sum of one hundred eight million nine hundred fifty-six thousand nine hundred sixty-one dollars ($108,956,961), plus interest in an amount of ten thousand four hundred forty eight dollars ($10,448) for each day beginning March 25, 2003 and continuing until and including the day before transfer is completed by Bayer to an escrow account pursuant to the State Escrow Agreement (the "State Settlement Amount"). The

State Settlement Amount shall be discharged pursuant to the State Escrow Agreement, and shall be transferred no later than seven business days after Bayer receives written transfer instructions from the negotiating team for the Participating States and following the latest of the dates on which the following occurs: (1) this Agreement is fully executed by the Parties and delivered to Bayer's attorneys, (2) the Court accepts the Fed. R. Crim. P. 11(c)(1)(C) guilty plea in connection with the Criminal Action and imposes the agreed upon sentence, or (3) the State Escrow Agreement is executed by or on behalf of the Participating States and Bayer.

C. Bayer shall pay to the PHS entities the sum of no less than nine million four hundred eighty-two thousand six hundred twenty dollars ($9,482,620), as further described in Paragraph 17 of this Agreement (the "PHS Settlement Amount"). The PHS Settlement Amount shall be paid by Bayer to each affected PHS entity by check on or before the latest of the following dates: (1) sixty (60) days after this Agreement is fully executed by the Parties and delivered to Bayer's attorneys, or (2) fifteen (15) days after the Court accepts the Fed. R. Crim. P. 11(c)(1)(C) guilty plea in connection with the Criminal Action and imposes the agreed upon sentence.

D. If Bayer's agreed upon guilty plea pursuant to Fed. R. Crim. P. 11(c)(1)(C) in the Criminal Action described in Preamble Paragraph G is not accepted by the Court or the Court does not impose the agreed upon sentence for whatever reason, this Agreement shall be null and void at the option of either the United States or Bayer. If either the United States or Bayer exercises this option, which option shall be exercised by notifying all Parties, through counsel, in writing within five business days of the Court's decision, the parties will not object and this Agreement will be rescinded. If this Agreement is rescinded, Bayer accepts service of the United States' Complaint-in-Intervention effective as of the date of recision, and waives any claim of defect regarding service of

process.

2. Subject to the exceptions in Paragraph 3 below, and in consideration of the obligations of Bayer set forth in this Agreement, conditioned upon Bayer's payment in full of the Settlement Amount, subject to Paragraph 16 below (concerning bankruptcy proceedings commenced within 91 days of the effective date of this Agreement), and subject to the acceptance by the United States District Court for the District of Massachusetts of Bayer's guilty plea described in Preamble Paragraph G, the United States, on behalf of itself, and its officers, agents, agencies, and departments, agrees to release Bayer, its current and former parents, affiliates, divisions, and subsidiaries, and their predecessors, successors and assigns, from any civil or administrative monetary claim that the United States has or may have under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; the Medicaid Rebate Statute, 42 U.S.C. § 1396r-8; the Drug Pricing Program, 42 U.S.C. § 256b; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; any statutory provision applicable to the Medicaid and PHS programs in this Agreement for which the Civil Division, Department of Justice has actual and present authority to assert and compromise pursuant to 28 C.F.R. Part O, Subpart I, 0.45(d)(1995); and common law claims for fraud, unjust enrichment, payment by mistake, breach of contract, or disgorgement for the Covered Conduct.

3. Notwithstanding any term of this Agreement, in this Agreement the United States specifically does not release Bayer, its current and former parents, affiliates, divisions, and subsidiaries, and their predecessors, successors and assigns, and its present and former directors, officers, agents, and employees from any and all of the following: (a) any criminal, civil, or administrative claims arising under Title 26, U.S. Code (Internal Revenue Code); (b) any criminal

liability; (c) any liability to the United States (or any agencies thereof) for any conduct other than the Covered Conduct; (d) any claims based upon obligations created by this Agreement; (e) except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs; (f) any express or implied warranty claims or other claims for defective or deficient products and services provided by Bayer; (g) any claims for personal injury or property damage or for other consequential damages arising from the Covered Conduct; (h) any claim based on a failure to deliver items or services due; or (i) any civil or administrative claims against individuals, including current and former directors, officers, and employees of Bayer, its current and former parents, affiliates, divisions, and subsidiaries, and their predecessors, successors and assigns.

4. In consideration of the obligations of Bayer set forth in this Agreement and the Corporate Integrity Agreement and Addendum thereto (collectively, "CIA"), conditioned on Bayer's payment in full of the Settlement Amount, and subject to Paragraph 16 below (concerning bankruptcy proceedings commenced within 91 days of the effective date of this Agreement), OIG-HHS agrees to release and refrain from instituting, directing, recommending or maintaining any administrative action seeking exclusion from the Medicare, Medicaid, or other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Bayer, its present and former parents, affiliates, divisions, and subsidiaries, and their predecessors, successors, and assigns under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) and 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion) for the Covered Conduct, except as reserved in Paragraph 3 above, and as reserved in this Paragraph. OIG-HHS further agrees to refrain from recommending or attempting to cause any administrative action or sanction, including suspension, debarment, contract termination, or contract non-renewal,

by any government agency for the Covered Conduct. The OIG-HHS expressly reserves all rights to comply with any mandatory statutory obligations to exclude Bayer from the Medicare, Medicaid, or other Federal health care program under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) regarding the Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which civil claims have been reserved in Paragraph 3 above.

5. The Relator agrees that the settlement of the Civil Action is fair, adequate, and reasonable under all the circumstances, and agrees not to challenge this Agreement pursuant to 31 U.S.C. § 3730(c)(2)(B), and expressly waives the opportunity for a hearing on any objection to this Agreement pursuant to 31 U.S.C. 3730(c)(2)(B). The Relator further agrees that this Agreement, and information relating to this Agreement and the Civil Action, may be made public.

6. Upon the United States' receipt of Bayer's payment of the Federal Settlement Amount, the Relator, Estate of George Couto, for itself and its successors, agents and assigns, and for the heirs of George Couto, and their successors, agents, and assigns, fully and finally releases, waives and forever discharges Bayer, its parents, divisions, affiliates and subsidiaries, and their predecessors, successors and assigns, and its current and former officers, directors, employees, agents and shareholders from any claim that the Relator has or may have that arises under or relates to the Civil Action and/or the Covered Conduct, except as they relate to a statutory claim for reasonable attorneys' fees, expenses and costs pursuant to 31 U.S.C. § 3730(d).

7. The United States agrees to pay the Relator, Estate of George Couto, an amount of thirty four million two hundred thirty six thousand five hundred thirty seven dollars ($34,236,537)(the "Relator's share"), plus three thousand sixty five dollars ($3,065) for each day

beginning March 25, 2003 and continuing until and including the day before complete payment is made by Bayer to the United States, as relator's share of the proceeds. The United States will pay the Relator's share within 21 days of receipt of payment of the complete Federal Settlement Amount from Bayer. Upon receipt of its relator's share, the Relator, Estate of George Couto, for itself, and its successors, agents, attorneys and assigns, and for George Couto's heirs, and their successors, agents, attorneys, and assigns, fully and finally releases, waives, and forever discharges the United States and the Participating States from any claims pursuant to 31 U.S.C. § 3730, including 31 U.S.C. §§ 3730(b), (c), (d), and (d)(1), and any state False Claims Acts, respectively, for a share of the proceeds of the Civil Action, from any claims arising from the filing of the Civil Action (including without limitation any claim to a share of any recovery that may be obtained by the United States and Participating States against any other defendant named by the Relator in his Complaint and Amended Complaint and thereafter voluntarily dismissed by the Relator); and in full settlement of his claims under this Agreement. This Agreement does not resolve or in any manner affect any claims the United States has or may have against the Relator arising under Title 26, U.S. Code (Internal Revenue Code), or any claims arising under this Agreement.

8. Within two business days after the Federal Settlement Amount is received, pursuant to and consistent with the terms of this Agreement, the United States and the Relator will file a stipulation of dismissal with prejudice in the Civil Action regarding all currently pending claims, with the sole exception of those statutory claims reserved by the Relator for reasonable attorneys' fees, expenses, and costs pursuant to 31 U.S.C. § 3730(d), which shall not be dismissed, unless those claims are settled and the Court is so informed by Bayer and the Relator.

9. Bayer waives and shall not assert any defense it may have to criminal prosecution or administrative action relating to the Covered Conduct, that is based in whole or in part on a contention that, under the Double Jeopardy Clause of the Fifth Amendment of the Constitution or Excessive Fines Clause of the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. Bayer agrees that this Agreement is not punitive in purpose or effect.

10. Bayer, on behalf of itself and its parents, divisions, subsidiaries, and affiliates, and their predecessors, successors and assigns, fully and finally releases, waives and discharges the United States, its agencies, employees, servants, and agents from any claims (including attorneys fees, costs, and expenses of every kind and however denominated) which Bayer has asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, related to or arising from the United States' investigation and prosecution of the Civil Action, the Criminal Action, and the Covered Conduct.

11. In consideration of the obligations of the Relator set forth in this Agreement, Bayer, on behalf of itself and its parents, divisions, subsidiaries, and affiliates, and their predecessors, successors and assigns, and its current and former officers, directors, employees, agents and shareholders, fully and finally releases, waives, and discharges the Relator and its successors, agents and agents, and the heirs of George Couto, and their successors, agents and assigns, from any claims Bayer has asserted, could have asserted, or may in the future assert against the Relator arising from the filing of the Civil Action and the United States' investigation and prosecution of the Civil Action, the Criminal Action, and the Covered Conduct.

12. The Settlement Amount that Bayer must pay pursuant to this Agreement shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare carrier or intermediary, any TRICARE Program ("TRICARE"), Federal Employees Health Benefit Programs ("FEHBP"), Veteran's Affairs Program ("VA"), Medicaid program payer, or any State payer, related to the Covered Conduct; and, if applicable, Bayer agrees not to resubmit to any Medicare carrier or intermediary, TRICARE, FEHBP, VA, Medicaid program or any state payer any previously denied claims, which denials were based on the Covered Conduct, and agrees not to appeal any such denials of claims.

13. Bayer agrees to the following:

a. Unallowable Costs Defined: that all costs (as defined in the Federal Acquisition Regulation ("FAR") 48 C.F.R. § 31.205-47 and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395ggg and 1396-1396v, and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Bayer, its parents, divisions, subsidiaries, or affiliates, and their predecessors, successors or assigns, and its present or former officers, directors, employees, and agents in connection with the following shall be "Unallowable Costs" on contracts with the United States and under the Medicare Program, Medicaid Program, TRICARE, VA and FEHBP: (1) the matters covered by this Agreement and the related plea agreement; (2) the United States' audit and civil and criminal investigation relating to matters covered by this Agreement; (3) Bayer's investigation, defense, and any corrective actions undertaken in response to the United States' audit and civil and criminal investigations in connection with the matters covered by this Agreement (including attorneys fees); (4) the negotiation and performance of this Agreement and the plea agreement; (5) the payment of the Settlement Amount and any payment that Bayer may

make to the Relator for costs and attorneys fees, and (6) the negotiation of and obligations undertaken pursuant to the CIA to: (a) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and (b) prepare and submit reports to the OIG-HHS. However, nothing in this paragraph affects the status of costs that are not allowable based upon any other authority applicable to Bayer.

b. Future Treatment of Unallowable Costs: If applicable, these Unallowable Costs shall be separately estimated and accounted for by Bayer and Bayer shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Bayer, its predecessor, parent, divisions, subsidiaries, or affiliates to the Medicare, Medicaid, TRICARE, VA, or FEHBP programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: If applicable, Bayer further agrees that within 60 days of the Effective Date of this Agreement, it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid, VA, and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid Program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Bayer, its parents, divisions, subsidiaries, or affiliates and their predecessors, successors or assigns shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. Bayer agrees that the United States shall be entitled to recoup from Bayer any overpayment, plus applicable interest, as a result of the

inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment. Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice, and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Bayer or its parents, divisions, subsidiaries or affiliates and their predecessors, successors or assigns on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Bayer or its parent, divisions, subsidiaries or affiliates' or their predecessors, successors or assigns' cost reports, cost statements, or information reports. Nothing in this Agreement shall constitute a waiver of the rights of the United States to examine or reexamine the Unallowable Costs described in this Paragraph.

14. Bayer agrees that it shall not seek payment for any of the monies owed under this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors. Bayer waives any causes of action against these beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims for payment covered by this Agreement.

15. Bayer expressly warrants that it has reviewed its financial condition and that it is currently solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I), and shall remain solvent following payment of the Settlement Amount. Further, the Parties expressly warrant that, in evaluating whether to execute this Agreement, the Parties (a) have intended that the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous exchange for new value given to Bayer within the meaning of 11 U.S.C. Section 547(c)(1), and (b) have concluded that these mutual promises covenants and obligations do, in fact, constitute such a contemporaneous

exchange. Further, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended and do, in fact, represent a reasonably equivalent exchange of value which is not intended to hinder, delay, or defraud any entity of which Bayer was or became indebted on or after the date of this transfer, all within the meaning of 11 U.S.C. § 548(a)(1).

16. In the event Bayer commences, or another party commences, within 91 days of the Effective Date of this Agreement, any case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors, (a) seeking to have any order for relief of Bayer's debts, or seeking to adjudicate Bayer as bankrupt or insolvent, or (b) seeking appointment of a receiver, trustee, custodian or other similar official for Bayer or for all or any substantial part of Bayer's assets, Bayer agrees as follows:

(a) Bayer's obligations under this Agreement may not be avoided pursuant to 11 U.S.C. §§ 547 or 548, and Bayer shall not argue or otherwise take the position in any such case, proceeding or action that: (i) Bayer's obligations under this Agreement may be avoided under 11 U.S.C. §§ 547 or 548; (ii) Bayer was insolvent at the time this Agreement was entered into, or became insolvent as a result of the payment made to the United States hereunder; or (iii) the mutual promises, covenants, and obligations set forth in this Agreement do not constitute a contemporaneous exchange for new value given to Bayer.

(b) If Bayer's obligations under this Agreement are avoided for any reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code, the United States, at its sole option, may rescind the releases in this Agreement, and bring any civil and/or administrative claim, action or proceeding against Bayer for the claims that would otherwise be covered by the releases provided in Paragraph 2 and 4, above. If the United

States chooses to do so, Bayer agrees that (i) any such claims, actions, or proceedings brought by the United States (including any proceedings to exclude Bayer from participation in Medicare, Medicaid, or other Federal health care programs) are not subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) as a result of the action, case, or proceeding described in the first clause of this Paragraph, and that Bayer shall not argue or otherwise contend that the United States claims, actions, or proceedings are subject to an automatic stay; (ii) Bayer shall not plead, argue, or otherwise raise any defenses under the theories of statue of limitations, laches, estoppel, or similar theories, to any such civil or administrative claims, actions, or proceeding which are brought by the United States within 90 calendar days of written notification to Bayer that the releases herein have been rescinded pursuant to this Paragraph, except to the extent such defenses were available on December 18, 2002; and (iii) the United States has a valid claim against Bayer in the amount of three hundred million dollars ($300,000,000), and the United States may pursue its claim, in the case, action, or proceeding referenced in the first clause of this paragraph or in such other claim, action or proceeding it chooses to commence.

(c) Bayer acknowledges that its agreements in this Paragraph are provided in exchange for valuable consideration provided in this Agreement.

17. To reimburse the PHS entities, Bayer agrees to recalculate its best price on Cipro tablets from Third Quarter 1995 through Third Quarter 2000, and to recalculate its best price for Adalat CC from Second Quarter 1997 through Third Quarter 2000, by including the prices for Cipro tablets and Adalat CC that were private labeled for Kaiser. Using its own data and records, Bayer further agrees to recalculate the maximum price that Bayer would have been allowed to charge the PHS entities based upon the impact of the newly calculated best price on the average Medicaid

rebate that it would have been required to pay for Cipro tablets from First Quarter 1996 through First Quarter 2001, and for Adalat CC from Fourth Quarter 1997 through First Quarter 2001 (the "redetermined price"). Within the time period described in Paragraph III.1.C. above, Bayer further agrees to reimburse each separate PHS entity which purchased the drugs from Bayer during the pertinent time period an amount equal to the product of (a) the units of each dosage form and strength of the drugs purchased by the PHS entity, and (b) the difference between the price originally paid by that PHS entity and the redetermined price (the "reimbursement owed"), which total amount will be not less than nine million four hundred eighty-two thousand six hundred twenty dollars ($9,482,620). Bayer agrees that the reimbursement owed to each entity will not be decreased by or offset against any amount the PHS entity owes Bayer. Bayer will pay the reimbursement to each entity by check, and will include on the check the phrase "In Full Satisfaction of 2003 Federal Settlement, Subject to the Terms of the Federal Settlement Agreement." Within 10 business days of completion of reimbursement of the PHS entities, Bayer will submit a report to the OIG-OAS at the following address:

Office of Audit Services, Office of Inspector General
Department of Health and Human Services
11300 North Rodney Parham, Suite 205
Valley West Building
Little Rock, Arkansas 72212
Attention: William Shrigley

that includes sufficient information and documentation as required by OIG-OAS to determine whether Bayer correctly calculated the reimbursement owed each PHS entity. If OIG-OAS requires any additional information or documentation to determine whether Bayer correctly calculated the reimbursement owed each PHS entity, Bayer agrees to provide the additional information or

documentation promptly upon request. If OIG-OAS determines that Bayer failed to include any PHS entity for which reimbursement was owed for the drugs in the relevant period, or underpaid the reimbursement owed to any PHS entity, OIG-OAS will notify Bayer in writing of the additional reimbursement owed. Within 30 days of receipt of the notification, Bayer agrees either to pay the additional reimbursement owed as identified by OIG-OAS, or to submit a request that OIG-OAS reconsider its determination based upon any additional information or documentation that Bayer wishes to submit. After reconsideration, OIG-OAS will determine the final reimbursement required to make each PHS entity whole, and Bayer agrees to pay such amount within fourteen (14) days of receipt of notification from OIG-OAS of the final reimbursement owed.

18. The Agreement is intended to be for the benefits of the Parties only, and by this instrument the Parties do not release any claims against any other person or entity.

19. Nothing in this Agreement constitutes an agreement by the United States concerning the characterization of the amounts paid hereunder for purposes of the Internal Revenue Laws, Title 26 of the United States Code.

20. Except as provided in Paragraph 6, each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

21. Bayer represents that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

22. Bayer has entered into a CIA with OIG-HHS, and that CIA is incorporated into this Agreement by reference. Bayer will immediately upon execution of this Agreement begin to implement its obligations under the CIA. A breach of the CIA does not constitute a breach of this

Agreement.

23. This Agreement is governed by the laws of the United States. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties under this Agreement shall be the United States District Court for the District of Massachusetts, including any dispute regarding Relators' attorneys' fees reserved in Paragraph 8, except that disputes rising under the CIA incorporated herein by reference shall be resolved exclusively through the dispute resolution provisions set forth in the CIA.

24. The undersigned Bayer signatory represents and warrants that he is authorized by the Board of Directors to execute this Agreement. The undersigned United States signatories represent that they are signing this Agreement in their official capacities and they are authorized to execute this Agreement through their respective agencies and departments. The undersigned signatory for the Relator represents and warrants that he is authorized and lawfully empowered to execute this Agreement on behalf of the Estate of George Couto. Relator, the Estate of George Couto, further warrants and represents that it possesses and controls all rights and interests in the claims and actions regarding the Covered Conduct and the Civil Action and that it is fully authorized to compromise and forfeit all such rights and interests without limitation.

25. The "Effective Date" of this Agreement shall be on the date of signature of the last signatory to the Agreement. Facsimiles of signatures shall constitute acceptable binding signatures for purposes of this Agreement.

26. This Agreement shall be binding on all successors, transferees, heirs, and assigns of the Parties.

27. This Agreement, together with the CIA incorporated by reference, and the plea agreement described in Preamble Paragraph G, constitute the complete agreement between the Parties with regard to the Covered Conduct. This Agreement shall not be amended except by written consent of the Parties, except that only Bayer and OIG-HHS must agree in writing to modification of the CIA.

28. This Agreement may be executed in counterparts, each of which shall constitute an original and all of which shall constitute one and the same Agreement.

UNITED STATES OF AMERICA

By: Susan Winkler
SUSAN G. WINKLER
Deputy Chief, Health Care Fraud
United States Attorney's Office
District of Massachusetts

Dated: 4/16/03

By: Andy Mao
ANDY J. MAO
Trial Attorney, Civil Division
United States Department of Justice

Dated: 4/9/03

By: _____
LARRY J. GOLDBERG
Assistant Inspector General for Legal Affairs
Office of Inspector General
U.S. Department of Health and Human Services

Dated:

27. This Agreement, together with the CIA incorporated by reference, and the plea agreement described in Preamble Paragraph G, constitute the complete agreement between the Parties with regard to the Covered Conduct. This Agreement shall not be amended except by written consent of the Parties, except that only Bayer and OIG-HHS must agree in writing to modification of the CIA.

28. This Agreement may be executed in counterparts, each of which shall constitute an original and all of which shall constitute one and the same Agreement.

UNITED STATES OF AMERICA

By: _____ Dated:
SUSAN G. WINKLER
Deputy Chief, Health Care Fraud
United States Attorney's Office
District of Massachusetts

By: _____ Dated:
ANDY J. MAO
Trial Attorney, Civil Division
United States Department of Justice

By: Larry J. Goldberg Dated: 4/9/03
LARRY J. GOLDBERG
Assistant Inspector General for Legal Affairs
Office of Inspector General
U.S. Department of Health and Human Services

BAYER CORPORATION

By: 

Dated: 4/4/03

JON R. WYNE
Senior Vice President and Treasurer
Bayer Corporation

By: 

Dated: 4/4/03

I. SCOTT BASS
PAUL E. KALB
NATHAN C. SHEERS
Sidley Austin Brown & Wood LLP
Counsel to Bayer Corporation

RELATOR
ESTATE OF GEORGE COUTO

By: Mark J. Couto
MARK J. COUTO
Co-Executor
Estate of George Couto

Dated: April 11, 2003

By: Joseph Couto
JOSEPH COUTO
Co-Executor
Estate of George Couto

Dated: April 11, 2003

By:
JAMES E. O'CONNELL, Jr.
Co-Executor
Estate of George Couto

Dated: April 11, 2003

By:
NEIL V. GETNICK
LESLEY ANN SKILLEN
Getnick & Getnick
Counsel to the Relator
Estate of George Couto

Dated:

RELATOR
ESTATE OF GEORGE COUTO

By: _____ Dated:
MARK J. COUTO
Co-Executor
Estate of George Couto

By: _____ Dated:
JOSEPH COUTO
Co-Executor
Estate of George Couto

By: _____ Dated:
JAMES E. O'CONNELL, Jr.
Co-Executor
Estate of George Couto

By: Neil V. Getnick Dated: April 11, 2003
NEIL V. GETNICK
LESLEY ANN SKILLEN
Getnick & Getnick
Counsel to the Relator
Estate of George Couto